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Prognosis of root canal treatments filled with Thermafil system: a 5-year retrospective study

Prognosi dei trattamenti endodontici otturati con Thermafil: studio clinico retrospettivo a 5 anni

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KEYWORDS
Clinical outcome;
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Root canal treatment;
Thermafil.

Abstract
Aim: The aim of this retrospective cohort study was to assess the clinical and radiographic outcome after 5 ± 1 years of root canal treatments filled with Thermafil (TF) and to evaluate if the success rate is consistent with results reported by Literature with standard techniques.
Methodology: A total of 213 endodontically treated teeth filled with TF and AH Plus were retrospectively examined. Following data were collected: initial pathology, primary treatment/retreatment and root filling length. Preoperative Periapical Index (PAI) was used as scoring system. At 5-years evaluation, teeth were judged *healthy* (PAI $\leq$ 2, no symptoms), *endodontically-diseased* (PAI $\geq$ 3 and/or symptoms, extraction or reintervention for endodontic reasons) or *not-endodontically-diseased* (root fracture, destructive caries, periodontal abscess). Outcome was blindly assessed by two examiners. Descriptive analysis and multivariate logistic regression were performed.

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Results: The total survival rate was 88%. Before the end-point, 20 teeth were extracted for not-endodontic reasons. Of the 193 analyzed teeth, 85% were considered *healthy* and proportions were significantly higher (Chi-square; $p < 0.04$) for teeth without initial radiolucency and when final length of root filling material was adequate. Logistic regression showed that the preoperative PAI ≤ 2 significantly increased the healing rate (risk ratio [RR] 3.09; 95% CI, 1.12—8.53).
Conclusions: The overall healing rate of the present investigation was similar to that previously reported by well-documented obturation techniques. The prognosis of endodontic therapies performed with TF obturation system supports the clinical use in a post-graduated Master Program.

PAROLE CHIAVE
Endodonzia;
Successo clinico;
Studio retrospettivo;
Prognosi;
Thermafil.

Riassunto
Obiettivi: Il presente studio clinico retrospettivo ha valutato il successo a 5 ± 1 anni di trattamenti endodontici eseguiti nel Master di Endodonzia e otturati con tecnica Thermafil (TF).
Materiali e Metodi: In totale, 213 denti trattati endodonticamente e inclusi nel Recall-program, sono stati esaminati durante le visite di controllo. I canali sono stati otturati con TF e cemento AH Plus. I seguenti dati sono stati registrati e analizzati statisticamente: patologia iniziale, tipo di trattamento (primo trattamento/ritrattamento) e lunghezza dell'otturazione canalare (underfilling, adeguato, overfilling). L'Indice Periapicale (Periapical Index-PAI) preoperatorio è stato usato come *scoring system*. Dopo 5 anni i denti sono stati classificati come *healthy* (PAI ≤ 2, nessun sintomo), *endodontically-diseased* (PAI ≥ 3 e/o sintomi; ritrattamenti, apicectomie o estrazioni per cause endodontiche) or *not-endodontically-diseased* (fratture radicolari, lesioni cariose profonde, problemi parodontali). La valutazione del risultato a 5 anni è stata effettuata in doppio cieco da due esaminatori esperti. L'associazione tra le variabili e il risultato finale è stata valutata statisticamente mediante analisi univariata e regressione logistica.
Risultati: La sopravvivenza a 5 anni è risultata 88% e l'85% degli elementi è stato classificato come *healthy* con valori statisticamente significativi (Chi-square; $p < 0.04$) in assenza di lesione periapicale iniziale e con un'otturazione canalare adeguata. La regressione logistica ha confermato il PAI iniziale ≤ 2 come fattore prognostico più importante (risk ratio [RR] 3.09; 95% CI, 1.12—8.53).
Conclusioni: Il successo delle terapie endodontiche eseguite con tecnica Thermafil e la notevole semplicità di esecuzione, ne incoraggiano l'utilizzo clinico all'interno di un Master di Endodonzia.

Introduction

Complete obturation and long-lasting seal of the root canal space represent a critical/fundamental step of successful root canal treatment. Warm gutta-percha compaction has been demonstrated as an efficient technique[1] with well-documented results.[2,3] However this technique is relatively difficult and time consuming[4] and requires a long training to be appropriately performed.

Among techniques using thermo-plasticized gutta-percha, Thermafil (TF) coated carrier system is gaining popularity over time. It was firstly described in 1978[5] and it consists of a plastic carrier, coated with α-phase gutta-percha,[6] utilized as a means of condensation.[7] This technique produces a homogeneous mass of gutta-percha, effective for obturating canals with curved morphology or difficult access. Available *in vitro* laboratory results deemed TF as an efficient technique able to ensure a stable long-term sealing,[4,8—11] comparable both to cold lateral[12—14] and warm vertical compaction[4,8] techniques. However, despite many laboratory studies and the ever-increasing clinical employment of the coated-carrier systems, to date there is little information about their clinical and radiological outcome. Few in vivo reports[15—17] are nowadays available concerning the clinical use of TF and the superiority of the carrier-based techniques in terms of clinical outcome has not been reported.

The aim of this 5-year longitudinal clinical study was to identify factors that might influence the prognosis of root canal treatment in teeth filled with TF observed in a retrospective cohort of patients during a Master Program of an University Endodontic Department. The present article was written following the STROBE Statement for observational studies and respecting the guidelines published by Dodson in 2007.[18]

Material and methods

Follow-up group

The study population consisted of patients recruited in the Dental Clinical School of DIBINEM — University of Bologna, Endodontic Department. Four-hundred twenty patients were treated by graduated attending the Master program of

Table 1 Considered variables are represented.

Parameters	Categories
Pre-operative parameters	
Gender	Female, male
Age	20—29, 30—39, 40—49, ≥50
Tooth location	Maxilla, mandible
Tooth type	Single rooted, premolar, molar
Initial diagnosis	Pulpitis, periapical lesion, preventive retreatment, therapeutic retreatment
Initial radiolucency	Absence, presence
Type of treatment	First treatment, retreatment
Intra-operative parameters	
Root filling length	Adequate, underfilling, overfilling

Endodontology from January 2008 to December 2010, and considered eligible for the present research. Only patients aged between 18-70, not affected by systemic disease, not treated with amino-bisphosphonates and with adequate oral hygiene (Plaque Index $<$ 20%) were included in the Recall program. Severely damaged teeth requiring periodontal therapy or included in a bridge were excluded. All patient recruited in this investigation were treated according with the principles established by the Declaration of Helsinki as modified in 2000.[19] A signed informed consent was obtained from all patients. Demographic and clinical data (age, gender, medical history, symptomatology, date of treatments) were extracted from medical records and radiographic parameters (PAI and length of root canal filling) were obtained from preoperative periapical radiographs (Table 1).

Root canal treatment

All root canal treatments were strictly standardized and performed by postgraduate students attending Master in Endodontics at the University of Bologna, under the supervision of experienced tutors. A preoperative periapical radiograph of the tooth was taken for every patient. Each element isolated with rubber dam (Hygienic Dental Dam, Coltène Waledent, Cuyahoga Falls, OH, USA) before creating a straight-line access. As a routine procedure for treatments and retreatments was used a step-down technique[20] with Gates-Glidden burs (Maillefer, Ballaigues, Switzerland) #4-3-2 at low speed. Coronal third and apical-medium third was prepared by using manual K-files (Maillefer, Ballaigues, Switzerland). Apical diameters were prepared between size ISO #20 and #45, depending on the size of the root. The working length was determined at 0.5 mm from the apex by electronic apex locator (Root ZX, Morita, Tokio, Japan) and radiographically confirmed. Each canal was irrigated with 5—10 ml of 5% NaOCl (Niclor 5, Ogna, Muggiò, Italy) and 1—3 ml of 10% EDTA (Tubuliclean, Ogna, Muggiò, Italy).

In case of root canal retreatment, the filling material was removed by using also appropriate solvents for gutta-percha and cement (Endosolv E or Endosolv R Septodont, Cedex, France) until the material was not detectable at naked eye and by radiograph.

Root canal filling and restoration

AH Plus sealer (Dentsply DeTrey GmbH, Konstanz, Germany) was mixed and inserted into root canal using a K-file. TF system (Dentsply Maillefer GmbH, Konstanz, Germany) was used as root canal filling procedure in all the included teeth. All root-treated teeth were temporized with Coltosol (Coltène Whaledent, Cuyahoga Falls, OH, USA) and received a permanent restoration within 2 weeks from root canal obturation.

A self-etching dentinal bonding agents (Clearfil SE BOND, Kuraray, Tokyo),a flowable composite resin and a high-filled composite resin (Gradia Direct, GC Corporation, Tokyo, Japan) was layered and photo-cured into the cavity. When considered necessary, a carbon post (Tech 2000 XOP, Isasan, Rovello Porro, Italy) was employed with Scotchbond 1/Relyx Arch (3 M ESPE, St. Paul, MN, USA). A provisional resin crown and a metal ceramic crown was considered on the basis of the residual tooth structure and applied after 3—6 month from endodontic therapy. Pre, intra, and post-operative radiographs were taken using the paralleling technique and only those with proper angulations and properly developed were accepted. The exposure time of each tooth type was standardized to minimize the radiation dose.

Outcome evaluation

One operator visited the patients, took the follow-up radiographs and recorded symptoms and clinical signs between October 2013 and December 2014. Periapical Index (PAI) firstly proposed by Ørstavik[21] was used to score each radiograph. The outcome assessment was performed by two examiners with the same years of training, blind to the preoperative data and the name of the patient. Teeth firstly treated were divided into two groups according to initial pulpal diagnosis and periapical status: vital teeth treated for pulpitis and deep carious lesions, necrotic teeth treated for periapical lesion. Retreated teeth were divided into two subgroups according to the absence/presence of initial signs/symptoms: preventive retreatments and therapeutic retreatments.

Obturation quality was evaluated on the basis of length of root filling material, classified as *adequate* (0—2 mm from the radiographic apex), *overfilling* (overextension of gutta-percha/sealer from the apex), *underfilling* ($>$2 mm from the apex). Multi-rooted teeth were scored depending on the root with the worst outcome. If the tooth had been extracted, the reason and the time of extraction were recorded. At the end-point evaluation, if the extraction was related to failure of the root canal therapy it was included in the main statistical analysis and if the extraction was for not-endodontic reasons (fractures or periodontal disease) it was excluded. Remaining teeth were dichotomized[22] as *healthy*, with a PAI $\leq$ 2 and no symptoms or clinical signs of illness,[21,23] or *endodontically diseased* (PAI $\geq$ 3, presence of symptoms or clinical signs of illness, undergone to further re-intervention before the end-point as orthograde or surgical retreatment, rizectomy or extraction due to endodontic pathology).

Statistical analysis

Bivariate analysis of the associations between the treatment outcome and clinical or radiographic parameters using

contingency tables and χ^2-square test was performed. Unconditioned logistic regression (forward method) was performed aiming to identify the best predictors of the outcome among the clinical and radiographic parameters examined that were significantly associated with the outcome on the basis of the bivariate analysis. α-Level was *a priori* set at 0.05. Subject's chart was examined to establish the date and the reason for extraction.

Results

A total of 213 teeth from 94 patients (48 females, 46 males; mean age: 48 ± 13 years) responding to all the inclusion criteria were collected and analyzed: 107 maxillary elements (50%) and 106 mandibular elements (50%) divided in 40 incisors and canines (19%), 65 premolars (30%), 108 molars (51%). The total 5-year survival rate was 88%. Twenty-six teeth were extracted before 5-years after treatment,. Six teeth (3%) were extracted for endodontic reasons (recurrent abscesses); 20 teeth (9%) were lost for not-endodontic reasons (periodontal reasons with pocket depth, periodontal abscesses or traumatic root-fractures) and excluded from the logistic regression analysis. A total of 193 teeth have been followed up for 5 years. All the parameters listed in Table 1 were correlated with the final outcome (healthy/diseased).

The overall healing rate was 85% and the percentage of diseased teeth after 5 ± 1 years was 15%.

The success rate was not significantly associated ($p > 0.05$) with gender, age, tooth type, maxillary and mandibular teeth nor with coronal restorations (Table 2). *Healthy* proportions were significantly higher for teeth with initial diagnosis of pulpitis and preventively retreated ($p = 0.0001$), in absence of radiolucency ($p = 0.0001$), when final length of root filling material was adequate ($p = 0.02$). Teeth primarily treated presented a success rate of 87%, higher than retreated teeth (80%), however the statistical significance was not reached.

Multivariate logistic regression identified, among the explicative variables significantly associated with the outcome, initial radiolucency (RR 3.09; 95% CI 1.12—8.53) as predictor of healing. Absence of radiolucency increased the healing rate of almost 3 times in comparison with presence of radiolucency.

Table 2 The association between primary outcomes and recorded variables is represented.

Variables	*n*	Healthy		
		n	%	*p* value
Pre-operative parameters				
Tooth location				0.462
Maxilla	101	84	83	
Mandible	92	80	87	
Tooth type				0.15
Single-rooted	40	32	80	
Premolar	63	58	92	
Molar	90	74	82	
Initial diagnosis				0.0001
Pulpitis	89	82	92	
Periapical Lesion	54	42	78	
Preventive retreatment	22	22	100	
Therapeutic retreatment	28	18	64	
Initial radiolucency				0.0001
Absence	111	104	94	
Presence	82	60	73	
Type of treatment				0.253
First treatment	143	124	87	
Retreatment	50	40	80	
Intra-operative parameters				
Root filling length				0.02
Adequate	117	106	91	
Overfilling	55	41	75	
Underfilling	21	17	81	
Total	193	164	85	

Discussion

Success of root-canal treatment has been defined as the prevention/elimination of periapical radiolucency and symptoms of endodontic origins. The presence of signs and symptoms of infection and the appearance/persistence of a lesion after the 4-year assessment period, is identified with post-treatment disease.[24] Nevertheless, it is extremely arduous to always define and categorize the outcomes of root canal treatments in terms of success or failure because clinical and radiographic signs can frequently appear unfocused.

This clinical study assessed the 5-year clinical outcome of endodontic therapies filled with TF by post-graduated Master students and evaluated if the success rate is comparable with gold standard techniques reported by Literature. The observation period of 5 ± 1 years was decided according to the Quality Guidelines for endodontic treatment by the European Society of Endodontology.[24] In fact a minimum period of 4 years is suggested as a cut off point for a dichotomous outcome assessment.

Retrospective investigations have been frequently used as the basis for further prospective studies. In the present clinical investigation, every root canal treatment was performed by trained postgraduates following well standardized and precise protocols. Chair-side time required for the obturation technique and the ease of manipulation of a material are fundamental factors that support the choice of TF technique in a Master of Endodontology. Selection of TF was also correlated with the operator experience and with the time required for filling procedure. In fact, TF has been shown to be an efficient technique, effective in obturing lateral canals[25] and results simple, fast and predictable especially in small or curved canals.[26] AH-Plus (Dentsply Maillefer, Ballaigues, Switzerland) is an epoxy-based endodontic sealer that *in vitro* provides a stable apical seal.[27]

Gagliani et al.[15] on 122 teeth obtured with TF, outlined a percentage of success of 95% in teeth without periapical lesion and of 48% with periapical radiolucency at 24 months. Chu et al.[16] examined 71 teeth after 3—4 years, finding similar treatment outcomes when TF was compared with cold lateral condensation of gutta-percha and reported the TF root canal filling requires significantly less operative time then lateral compaction. A more recent clinical study[17] verified the results of 71 primary endodontic treatments filled with lateral compaction or carrier-based obturation, finding that the tooth type significantly affected outcome, irrespective to the used obturation technique.

Intricate anatomies and complex operative procedures make challenging the treatment of multi-rooted teeth. Whilst technology has improved instruments and materials to achieve rising outcomes in root canal therapies, it is astonishing that the reported success rates have failed to increase over the last four or five decades.[28] A possible explanation could be the selection of more complex cases supported by confidence in better skills of specialized clinicians and by the tendency in preserving natural teeth. The overall healing rate of the present investigation was 85%: it should be emphasized that those findings are similar to that previously reported by using well-documented obturation techniques.[3,29–32]

Among analyzed pre- and intra-operative factors, the following variables resulted to significantly affect the outcome: initial diagnosis, presence/absence of pre-operative radiolucency and length of root filling material. As expected, the present research confirmed that teeth without preoperative radiolucency resulted in a favourable percentage of healing (94%). Concerning initial diagnosis, only 8% out of vital teeth were classified as "failure", revealing the onset of a periapical lesion after 5 years. The outcome was lower in teeth with pre-operative radiolucency, thus confirming[2] this condition as an important factor enhancing the healing rate of root canal treatments. A relevant percentage (27%) of teeth with initial periapical lesion were classified as *endodontically-diseased* at the end point: 6 out of these were extracted because resulted not re-treatable and antibiotic not-sensitive. In the present study, the concurrence of overfilling and pre-operative periapical lesion did not statistically diminish the chance of healing. Those data are in contrast with Tennert et al.[33] who demonstrated that the use of TF increases root canal filling extrusion and hypothesized negative effects of overextension.

Although bivariate analysis showed a negative effect of preoperative conditions (initial diagnosis, pre-operative radiolucency) and a post-operative factor (length of root filling material), in the logistic regression only the presence of a preoperative periapical lesion had significant effect. Periapical lesions are concomitant with the presence of bacteria population that harbours the entire canal systems[30,34,35] insisting on the periapical tissue.[36]

Conclusions

TF system with AH Plus cement can be deemed as an ultimate/suitable obturation method in a post-graduate Master Program. It was appealing to notice that the healing rate was similar than those reported by Literature. This observation encourages the clinical use of TF.

Conflict of interest

The authors deny any conflict of interest

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